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13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*

This project is conducting a randomized double-blind clinical trial to assess the ability of a soy protein dietary supplement to reduce prostate cancer risk in older men. A total of 120 men (60 white men and 60 African-American men) aged 50 years or older with high PSA levels but normal prostate biopsies will be randomized into one of two groups (soy protein supplementation with isoflavones or casein protein supplementation). The specific aims are: 1) to determine the impact of the interventions, including changes in clinical (PSA levels and prostate volume) and intermediate (Ki-67, apoptosis, sex-steroid receptors, angiogenesis, antioxidant enzyme expression) markers of prostate cancer risk; 2) to assess soy protein effects on hormone levels, plasma lipids/lipoproteins and blood pressure; and 3) to evaluate changes in health-related quality of life, including urinary symptoms and sexual functioning. This project involves a multidisciplinary team affiliated with the cooperative group, Cancer and Leukemia Group B (CALGB), which has substantial expertise in controlled clinical trials, oncology, epidemiology, health-related quality of life, biostatistics, and nutrition. NCI approval of the CALGB protocol delayed start-up of this study; recruitment has been continuous since March 2000. Limited access status has changed to include all CALGB member institutions in recruitment.

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INTRODUCTION:

Soybeans and other legumes contain large amounts of plant estrogens known as isoflavones. Specific isoflavones found in soy (genistein and diadzein) have been implicated in reducing breast, colon, and prostate cancer risk in both laboratory-based studies (1). Strong evidence for an effect on prostate cancer risk comes from cross-cultural studies which have shown that prostate cancer rates are much lower in the Pacific Rim countries where soy products comprise a much higher proportion of the normal diet compared to the United States (2). This study proposes to conduct a randomized double-blind clinical trial which will assess the ability of a soy protein dietary supplement (a rich source of isoflavones) to reduce prostate cancer risk in older men. This project will randomize 120 men (60 white men and 60 African-American men) aged 55 years or older with high PSA levels but normal prostate biopsies into one of two groups (soy protein supplementation with isoflavones or casein protein supplementation). The specific aims of the study are: 1) to determine the impact of the interventions on the prostate, including changes in clinical (PSA levels and prostate volume) and intermediate (Ki-67, apoptosis, sex-steroid receptors, angiogenesis, antioxidant enzyme expression) markers of prostate cancer risk (3,4); 2) to assess soy protein effects on hormone levels, plasma lipids/lipoproteins and blood pressure; and 3) to evaluate changes in health-related quality of life, including urinary symptoms and sexual functioning. This project will involve the collaborative efforts of a multidisciplinary team affiliated with the cooperative group, Cancer and Leukemia Group B (CALGB), which has substantial expertise in the areas of controlled clinical trials, oncology, epidemiology, health-related quality of life, biostatistics, and nutrition. If positive results are obtained in this trial, soy supplementation may provide an important tool for the prevention of prostate cancer.

BODY:

ACCOMPLISHMENTS ASSOCIATED WITH THE APPROVED STATEMENT OF WORK

Task 1:

a. Annual renewal of the consent, study forms and questionnaires that were developed and approved by the CALGB and NCI.
b. Wake Forest University School of Medicine disseminated the Soy and Casein supplements received from PTI to the participating sites.
c. Staff training sessions continues to be held in conjunction with the annual meetings of the CALGB. All sites have not had the opportunity to attend; however staff have been identified and contacted at each of the remote sites. Training for the sites that did not attend the annual meetings will be done via phone.

Task 2:

a. Four sites within CALGB have been recruited to participate. We are selecting additional sites currently.
b. The recruitment phase has been slow due to the changes in the procedures to complete prostate biopsies. More samples are being gather and more likely than not, if a biopsy is performed, the diagnosis is 90% positive.
c. Discussion and approval from the urology clinic physicians to begin the screening of their patients coming in for biopsies has been accomplished. However because of standing contracts many private urologists are pulling away from the low paying projects to use their patients for the higher income projects.

KEY RESEARCH ACCOMPLISHMENTS:

Sites completed their individual Institutional Review Board approvals and began recruitment. Wake Forest University School of Medicine shipped product to all sites. Samples obtain to this point are being batched at Ralston for tests to be run collectively. We have also secured arrangements with MD Anderson to use a Food Frequency with added soy-containing foods for this study. We have opened the study to the whole membership of the CALGB as an answer to the slow recruitment numbers. We have recruited four participants. Our longest participant has an excellent adherence record. We anticipate increasing accrual with opening this up to all of our CALGB sites and our upcoming training session at the CALGB meeting.

REPORTABLE OUTCOMES:

None to report during this annual reporting period.

CONCLUSIONS:

Although this should be the final report at this time we have requested and received a no cost extension of this study. First our protocol was delayed over 14 months at the NCI. Then we had to wait longer for CALGB approval, activation and institutional (not WFUSM) IRB approvals. Task 2 has been slowed dramatically due to the current prostate biopsy guidelines; more of the biopsies that are being performed because of elevated PSA test results are positive. This has reduced the number of eligible men for this study. With the opening of the study to all CALGB sites, we should have better recruitment.

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APPENDICES:

None.